

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/402,737 10/08/99 NEUSER

D BAYER10197

HM12/1010

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EXAMINER

GEORGE, K

ART UNIT	PAPER NUMBER
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1616

18

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/402,737	NEUSER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Konata M. George	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-12 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Claims 1-12 are pending in this application.

### ***Action Summary***

1. The rejection of record under 35 U.S.C. 103(a) over Griffin is being maintained for the reasons stated in the previous office action.

### ***Response to Arguments***

2. Applicant's arguments filed September 21, 2001 have been fully considered but they are not persuasive.

Applicants argue that Griffin's combination of a pain reliever outer layer and an antihistamine is different from what is claimed. It is the position of the examiner that Griffin teaches the claimed invention. As pointed out by applicant column 4, lines 37-40, describes a two-stage coated capsule that may have a treatment for a sore throat and a pain reliever *or* antihistamine. It is the position of the examiner that both agents are analgesics.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 5,702,723) in view of Nelson (US 4,446,140).

Griffin discloses a multiple therapeutic substances delivered in a single pill for oral administration. The outer layer comprising an active substance of substance that will dissolve and have a beneficial effect somewhere is the mouth or upper respiratory area with the subsequent layers dissolving and the contained substances acting deeper within the body such as in the gastro-intestinal area or systemically (col. 3, lines 3-13). The prior art discloses several examples throughout the specification, one specific example comprises a pain reliever that has a rapid absorption and an antihistamine with acts systemically (col. 4, lines 24-36). The prior art does not disclose a time of onset action or that the composition also contains ancillary substances and carriers.

Nelson discloses a method and composition for treating mouth pain. The prior art teaches that it has discovered that dextromethorphan is useful in the treatment of mouth pain in the temporary reduction of such pain (col. 1, lines 37-41). It is the opinion of the examiner that dextromethorphan used in this invention is acting or has the properties of an analgesic. The invention further contains in addition to the dextromethorphan a conventional analgesic or anesthetic such as ibuprofen, naproxen or butacaine (col. 1, lines 49-57 and col. 2, lines 18-32). The pharmaceutical composition may be in the form suitable for oral use (col. 2, lines 52-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was use the combine teachings of Griffin and Nelson to arrive at the claimed invention. Both references teach an oral administration of a local and a systemically acting agent with delivers immediate action and sustained release action as claimed in the instant invention.

(S, 111) 19

***Conclusion***

4. Claims 1-12 stand rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiries***

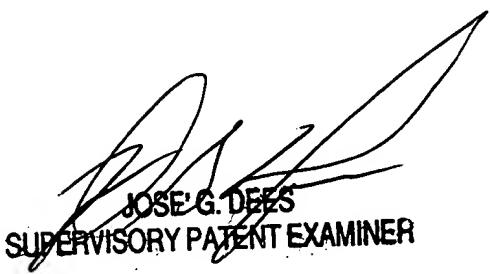
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

1616